

REMARKS

I. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 3-5 stand rejected under 35 U.S.C. §112, first paragraph, because the Examiner alleges that the specification, while being enabling for treatment of poor hair growth or alopecia, does not reasonably provide enablement for prevention of poor hair growth or alopecia. However, the claims do not require prevention of poor hair growth or alopecia by the recited method. Specifically, claims 3-5 are directed to methods for "at least assisting in preventing or treating poor hair growth" in animals in need of such treatment. As described in the specification, for example, at paragraph 0008 on page 3, "enhancing hair growth with selenium supplementation can benefit the management of disorders of the skin, hair follicle and/or hair coat by preventing or treating poor hair growth or alopecia" Further, Applicants have demonstrated by working example that dogs fed selenium in accordance with the methods of the invention had higher rates of hair growth than dogs fed diets with more or less selenium. Thus, one skilled in the art would understand, from reading the specification as a whole, that the present methods which demonstrated increased hair growth will "at least assist in preventing" or treating poor hair growth or alopecia, such that claim 3 is sufficiently enabled.

Additionally, Applicants have clearly articulated both how to make and use the treatment of claim 3, including how to use the treatment to at least assist in preventing poor hair growth or alopecia. For example, at page 2, lines 22-30, Applicants specifically set forth the means for determining the quantity of selenium to be used in the treatment. Applicants also clearly state that the selenium can be administered in an animal's diet or through specific supplements to be fed to the animal. See, e.g., page 2, line 35 to page 3, line 2. Accordingly, it is submitted that one skilled in the art could make or use the invention from the disclosures in the specification coupled with information known in the art such that undue experimentation is not necessary. Thus, Applicants respectfully submit that claim 3 is sufficiently enabled such that the rejection under 35 U.S.C. §112, first paragraph, has been traversed.

Claims 4 and 5, which depend in whole or in part from claim 3, are submitted to be enabled under 35 U.S.C. §112, first paragraph, for at least the reasons set forth with respect to claim 3. Reconsideration and withdrawal of the rejection is requested.

III. Rejection Under 35 U.S.C. §102(b)

Claims 3 and 4 stand rejected under 35 U.S.C. §102(b) as being anticipated by McDonald. Applicants respectfully submit that the rejection is traversed.

Applicants respectfully submit that the Examiner has erred in maintaining an anticipation rejection. In particular, Applicants have amended claim 3 in prior prosecution such that the claim requires the administration of from about 0.5 to about 4.5 mg of selenium per kg of diet on a dry matter basis for at least assisting in preventing or treating poor hair growth or alopecia in animals in need of such treatment. The cited reference, McDonald, reports a trial in which 0.1 mg selenium per kg body weight was given orally to ewes and/or lambs at three month intervals. *See* page 433. Because McDonald does not teach the administration of more than 0.1 mg selenium per kg body weight, the reference does not teach each and every element of claim 3. Further, one skilled in the art reading the application and subsequent prosecution would understand that the limitation of "about 0.5" does not subsume 0.1 as required by McDonald. Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Claim 4, which depends from claim 3, is submitted as patentable over the cited reference for at least the same reasons set forth with respect to claim 3.

IV. Rejection Under 35 U.S.C. §103

Claims 2-5 stand rejected under 35 U.S.C. §103(a) as obvious over WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger. Applicants have traversed the rejection for the reasons set forth below.

Applicants submit that claims 2-5 are patentable over the combination of WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger because the Office has failed to establish a *prima facie* case of obviousness. In particular, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings to practice the present invention. WO 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger, taken either alone or in any combination, do not teach or suggest administering from about 0.5 to about 4.5 mg selenium per kg of diet to an animal for at least assisting in preventing or treating poor hair growth or

alopecia or for controlling the rate of hair growth in a dog, cat, or sheep as recited in instant claims 2 and 3.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings and the references, when combined, must teach or suggest all the claim limitations. *See* MPEP §2143. Further, obviousness must be reviewed from the perspective of one skilled in the art at the time of the invention without the benefit of hindsight. *Tyco Indus. v. Tiny Love, Ltd.*, 914 F. Supp. 1068, 1079 (D.N.J. 1996). Thus, there must be a teaching or suggestion in the prior art, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources of information, to select particular elements, and to combine them in the way they were combined by the inventor. *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ 1321, 1329 (Fed. Cir. 1998). Determination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention. *Id.*

In the instant application, the Examiner has relied on seven references to recreate the present invention. Although the Examiner acknowledges that the cited art does not expressly disclose the methods of the present invention as previously argued by the Applicants, the Examiner has maintained his obviousness rejection. In particular, at page 5 of the final Office action, the Examiner contends that the cited art suggests the methods of the present invention because the references disclose (1) that selenium is critical to wool production (Lee et al.), (2) that selenium is given as a nutritional supplement to animals (WO 98/11122; Shields Jr. et al.; Hayek et al.), (3) that selenium deficiency results in T3 deficiency (Arthur et al.), (4) that T3 stimulates hair cell growth and/or metabolism (Ahsan et al.) and (5) the administration of thyroxine, which is converted to T3 by an enzyme which requires selenium, is effective in growing hair in sheep and badgers (Messenger). The Examiner continues to conclude that "as such it would be well within the skill of and one of ordinary skill in the art would have been motivated to administer similar amounts of selenium to dogs or cats with the expectation that selenium administration would control the rate of hair growth or treat poor hair growth or alopecia." (Emphasis added).

Applicants respectfully submit that the Examiner has erred in his conclusions. The cited references do not remotely teach or suggest the methods of the present invention such that one skilled in the art would expect selenium administration to control the rate of hair growth or treat poor hair growth or alopecia. Instead, the Examiner is attempting to combine seven isolated references to fit the parameters of the present invention. Nothing in any of the references supports the combination of any two references, much less all seven. Thus, the Examiner is relying on Applicant's own disclosure to import the requisite teachings and motivation necessary to combine the references. Accordingly, Applicants submit that the Examiner's conclusions are based on impermissible hindsight.

Even if a motivation to combine the references could arguably be established, nothing in the cited references teaches or suggests administering the amounts or ranges of selenium recited in instant claims 2 and 3. The cited references discuss various amounts of selenium (0.1 to 0.3 mg in Lee et al.; 0.4 mg/kg in Shields, Jr. et al.; 0.27 mg/kg in Hayek et al.; 0.001 mg to about 5 mg in WO 98/11122) in various nutritional supplements. Applicants respectfully submit that such disparate individual teachings are insufficient to arrive at the Applicant's range of from about 0.5 to about 4.5 mg selenium per kg of diet as recited in the instant claims. Further, even if the amounts of selenium are "similar" as argued by the Examiner, Applicants have demonstrated in Example 1 at pages 3-5 of the specification that dogs fed selenium in accordance with the methods of the invention had higher rates of hair growth than dogs fed diets containing amounts of selenium outside of the claimed range. Thus, without reference to Applicant's results, one skilled in the art would not interpret the disparate teachings of the cited references, which contain amounts outside of the claimed ranges, as teaching or suggesting the claimed range of from about 0.5 to about 4.5 mg selenium per kg of diet. Accordingly, any combination of the cited references is insufficient to teach or suggest all of the claimed limitations such that a *prima facie* case of obviousness cannot be established.

In sum, Applicants submit that there is no suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings, and even if combined the references do not teach all of the claimed limitations such that a *prima facie* case of obviousness cannot be established. Thus, claims 2 and 3 are not obvious under 35 U.S.C.

§103(a) over any combination of 98/11122, Lee *et al.*, Shields, Jr. *et al.*, Hayek *et al.*, Arthur *et al.*, Ahsan *et al.*, and Messenger.

Because a *prima facie* case of obviousness cannot be established for independent claim 3, it is respectfully submitted that a *prima facie* case of obviousness cannot be established for claims 4 and 5, which depend from independent claim 3. Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is requested.

V. Conclusion

In summary, the rejections under 35 U.S.C. §102(b), §103(a), and §112 have been obviated or overcome. In view of the foregoing remarks, it is submitted that the claims are in condition for allowance. Reconsideration of the application is requested and allowance of the claims at an early date is solicited.

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to call the undersigned at the number listed below.

Respectfully submitted,

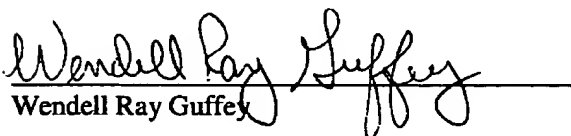


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I hereby certify that this correspondence is being transmitted by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 13, 2006 at facsimile number 571-273-8300.



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